DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 23, 2015

CareFusion
Ms. Joy Greidanus
Manager, Regulatory Affairs
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K141722
Trade/Device Name: CareFusion Gold Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: December 11, 2014
Received: December 15, 2014

Dear Ms. Greidanus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141722

Device Name
CareFusion Gold Tissue Marker

Indications for Use *(Describe)*
The CareFusion Gold Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY K141722

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion
Address	75 North Fairway Drive, Vernon Hills, IL 60061 USA
Phone number	(847) 362-8103
Fax number	(312) 949-0583
Establishment Registration Number	1423507
Name of contact person	Joy Greidanus
Date prepared	January 14, 2015
DESCRIPTION OF DEVICE	
Trade or proprietary name	CareFusion Gold Tissue Marker
Common or usual name	Tissue Marker
Classification name	Implantable Clip
Classification panel	General & Plastic Surgery
Regulation	Class II per 21CFR §878.4300, Procode NEU
Product Code(s)	Multiple
Legally marketed device(s) to which equivalence is claimed	K070436 Carbon Medical Technologies
Reason for 510(k) submission	New product.
Device description	The Gold Tissue Marker is a sterile, single use device comprised of a gold marker and disposable delivery device. The delivery device has 1cm reference marks and echogenic marks on the distal tip to aid in ultrasound guided marker placement. The Gold Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.
Intended use of the device	The Gold Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**New Device**	**Predicates**
Delivery device	Manual mechanism (plunger action) with stylet and cannula	Same as predicate: K070436 Carbon Medical Technologies
Tissue marker	Implanted, gold	Same as predicate: K070436 Carbon Medical Technologies
Visualization	Visible on standard radiographs, Magnetic Resonance Imaging (MRI) and ultrasound	Same as predicate: K070436 Carbon Medical Technologies

CONCLUSION OF DEVICE COMPARISON	
The technological characteristics of the proposed devices are substantially equivalent to the predicate.	
PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
Characteristic	Standard/Test/FDA Guidance
Biocompatibility	AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing
Biocompatibility	AAMI/ANSI/ISO 10993-6: 2007 (R) 2010 Biological Evaluation of Medical Devices – Part 6 Tests for Local Effects After Implantation
Residuals	AAMI/ANSI/ISO 10993-7:2008 Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
Biocompatibility	AAMI/ANSI/ISO 10993-11: 2006 Biological Evaluation of Medical Devices – Part 11 Tests for Systemic Toxicity
Biocompatibility	AAMI/ANSI/ISO 10993-18: 2006 Biological Evaluation of Medical Devices – Part 18 Chemical Characterization of Materials
Performance	ISO 14630: 2012: Non-active Surgical Implants - General Requirements
Performance	ASTM F72: 2006 Section 4: Standard Specification for Gold Wire for Semiconductor Lead Bonding
Performance	ASTM F2052: 2006: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment
Performance	ASTM F2119: 2007: Standard Test Method for the Evaluation of MR Image Artifacts from Passive Implants
Performance	ASTM F2182: 2011A: Standard Test Method for the Measurement of Radio frequency Induced Heating on or Near Passive Implants During MRI
Performance	ASTM F2213: 2006, RA 2011: Standard Test Method for the Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment
Performance	BS EN ISO 9626:1995: Stainless Steel Needle Tubing for the Manufacture of Medical Devices.
Performance	ISO 11737-1,2:2006 Sterilization of Medical Devices – Microbiological Methods Part 1 & 2
Performance	ISO 11135:2007 Medical Device, Validation and Routine Control of Ethylene Oxide Sterilization
Performance	AAMI TIR28:2009 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
Performance	Bench Top Testing – Marker securement, force to deploy, dimensional verification, and strength of connections
Performance	Simulated Use – Implantation, visualization under ultrasound, MRI and radiograph, marker integrity after repeated compression
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
N/A – No clinical tests were conducted for this submission	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
The results of the non-clinical tests show that the CareFusion Gold Tissue Marker meets or exceed all performance requirements, and is substantially equivalent to the predicate devices.	